Nos. 23-2989 & 23-3965

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff – Appellee,

v.

MARK SCHENA,

Defendant – Appellant.

Appeal from the United States District Court
for the Northern District of California, San Jose
Honorable Edward J. Davila, District Judge, Presiding
No. 20-CR-00425-EJD

APPELLANT'S OPENING BRIEF

Leah Spero
SPERO LAW OFFICE
912 Cole Street, No. 301
San Francisco, CA 94117
Telephone: (415) 343-5563
leah@sperolegal.com

Attorney for Appellant
Mark Schena

TABLE OF CONTENTS

Page

TABLE OF CONTENTS (cont.)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES (cont.)

Page(s)

Cases

Statutes

TABLE OF AUTHORITIES (cont.)

Page(s)

Rules and Regulations

Other Authorities

INTRODUCTION

The government prosecuted Mark Schena for several business practices and public statements related to his company, Arrayit, which used microarray technology to detect allergy and Covid antibodies in small blood samples that could be obtained through a finger prick rather than a typical blood draw. While the government painted the picture of widespread, calculated fraud throughout the business, the defense painted the picture of a mom-and-pop operation that Schena and his wife ran together, along with a small group of family and friends, and without much experience in the complex regulatory rules and procedures that apply to clinical laboratories.

At trial, the government introduced evidence of several allegedly fraudulent acts and omissions over a five-year period, but the charges against Schena focused on a much narrower set of acts. Whatever the evidence at trial could have been used to prove, it simply did not support six of the nine counts against Schena. And the other three counts against Schena were affected by an erroneous jury instruction. Thus, all of the counts against Schena must be reversed.

First, the government's theory that Arrayit paid illegal kickbacks to independent marketers in the form of commission payments fails as a matter of law for purposes of Counts 4–6. The anti-kickback statute at issue criminalizes paying someone in return for corruptly referring patients to a lab for services because of the financial inducement of the kickback. However, the commission payments to marketers did not corruptly induce a referral: the marketers did not, and could not, make referrals; only physicians could make referrals, and the physicians did not receive any compensation for doing so.

The government's expansive reading of the anti-kickback statute to include paying someone in return for marketing to a medical provider, who independently decides whether or not to make a referral, cannot be squared with the ordinary meaning of a "kickback." This expansive reading also contradicts the statutory context and the restraint required for criminal statutes. Separately, even if the Court were to uphold this theory of liability, the kickback convictions would have to be reversed because the government elicited improper and prejudicial legal testimony from several witnesses, who opined that the commissions to marketers constituted unlawful kickbacks.

Second, the evidence failed to establish that three specific public announcements made by Arrayit, as identified in Counts 7–9, amounted to securities fraud. These announcements either (i) did not misstate the facts at the time, when read in full, or (ii) were not material in the sense that they would alter a reasonable investor's trading decisions. And although the government put on evidence of other purportedly false statements, the indictment and the verdict form focused the jury on the three announcements at issue—not on any other statements or over-arching securities fraud scheme.

Third, the government's core theory at trial was healthcare fraud, but, for these counts (Counts 1–3), the jury received an improper instruction that negated the mens rea requirement. According to the government's theory, Arrayit overbilled medical insurance providers because it tested all blood samples for 120 allergens and, later, bundled its allergy test with its Covid test, despite the lack of medical necessity for either of these practices. For a conviction, the government had to prove that Schena knew these practices were unlawful. Yet the erroneous jury instruction stated the opposite: that the government *did not* have to prove knowledge of unlawfulness. Because a properly

instructed jury might not have found, beyond a reasonable doubt, that Schena had such knowledge, the instructional error requires reversal. This same instructional error affected the kickback counts, although, as already explained, those counts suffer from other problems, as well.

Finally, the nearly $25M restitution order improperly includes losses untethered from offense conduct, as does the forfeiture order. Because both monetary penalties *must* be tied to offense conduct, they cannot stand, even if the related convictions are affirmed.

Accordingly, the Court should reverse all counts of conviction and, separately, should vacate the restitution and forfeiture orders.

JURISDICTION AND BAIL STATUS

The district court had jurisdiction under 18 U.S.C. § 3231 and orally imposed judgment on October 18, 2023. 1-ER-239. Schena filed a notice of appeal on October 23, 2023. 10-ER-2685. The court entered written judgment on November 17, 2023, and later amended the judgment to correct a clerical error. 1-ER-2–11. Schena's notice of appeal is therefore timely. Fed. R. App. P. 4(b)(2). This Court has jurisdiction under 28 U.S.C. § 1291. Schena is serving his sentence at Atwater USP with a projected release date of November 15, 2030.

ISSUES PRESENTED

I. Do Arrayit's commission payments to marketers fail to qualify as illegal kickbacks to induce referrals under EKRA?

II. Alternatively, did the district court abuse its discretion by admitting witness testimony expressing legal conclusions about the application of EKRA to marketer payments?

III. Did the district court err by giving the wrong jury instruction to define "knowingly" for Counts 1–6, which negated the knowledge-of-unlawfulness requirement?

IV. Is the evidence insufficient for the securities fraud counts?

V. Did the district court err by imposing restitution and forfeiture for losses untethered from offense conduct?

STATEMENT OF THE CASE

A. Arrayit technology and lab services.

Schena founded Arrayit based on microarray technology that can detect antibodies (which indicate allergies and infections) in a small sample of blood obtained with just a finger prick. 10-ER-2636–37, 10-ER-2644, 6-ER-1726–30. This technology improves upon traditional blood testing that requires much larger blood samples, usually obtained

in a lab setting detached from a physician's office. 9-ER-2627. Originally, Arrayit sold the microarray technology to other labs and medical companies, but in 2017 decided to open a lab for processing its own allergy blood tests. 5-ER-1173–75.

Schena created a microarray chip that comprehensively tested for 120 different allergens ranging from grass and tree allergens, to food allergens, to pet and insect allergens. 2-ER-498–99; 10-ER-2635–36. This 120-allergen test was made available through simple sample-collection kits that physicians could use in their own offices. 10-ER-2638–39. The physicians or their staff would prick a patient's finger with the lancet provided, press four drops of blood onto the card provided, mail it to Arrayit's lab for processing in the envelope provided, and receive the results within a few days. 10-ER-2638–39.

Schena's wife served as CEO, and they had a small staff of mostly family and friends. 5-ER-1161, 5-ER-1168–69. The microarray machines at Arrayit's lab processed the blood samples and produced the allergy reports through an automated procedure, and, thus, few workers were needed in the lab other than Schena. 3-ER-721–22, 6-ER-1726–

30. As one witness described Arrayit, it was a "mom and pop small business." 6- ER-1645.

For several aspects of the business, Arrayit relied on experienced outside professionals: to market the test kits, to handle the billing, to help with regulatory matters, to advise on applicable laws, to register Arrayit with insurance providers, and to prepare and audit its financial statements. 2-ER-442–43, 3-ER-627, 3-ER-737, 4-ER-971, 5-ER-1165–66, 5-ER-1307, 5-ER-1440, 10-ER-2654. Arrayit did not have written agreements with all of these consultants and could not always pay them on time or in full when money was tight. 3-ER-628, 4-ER-1056, 4-ER-1061, 5-ER-1166, 5-ER-1227, 10-ER-2654.

Arrayit's outside billing agent would bill the applicable insurance company for each blood sample that Arrayit processed. 5-ER-1204–05. The insurance companies had different reimbursement rates and paid only a fraction of the amount billed or, in several instances, rejected the claim and paid nothing at all. 5-ER-1206, 9-ER-2620. For an allergy blood test to be covered by insurance, a physician must determine that the test is medically appropriate for the patient. 2-ER-409–10, 2-ER-441, 2-ER-447. Labs do not, and cannot, make this decision. *Id.*

While skin testing is the most cost-effective method for allergy testing, and thus insurers' first choice, blood tests can be medically appropriate in several situations, including when a patient has an adverse reaction to a skin test and when the suspected allergy cannot be detected with a skin test. 2-ER-410, 2-ER-495, 7-ER-1888. Arrayit improved upon traditional allergy blood tests, which require much larger blood samples that often cannot be taken in a physician's office, and which require a longer time to process. 10-ER-2636–44.

For most of the relevant time period, Arrayit tested all blood samples for all of the 120 allergens included in the microarray chip. 3-ER-648. Some physicians wanted Arrayit to provide an option to test for fewer allergens, but Schena did not want to reduce the number. *Id*. Nonetheless, physicians had many other skin and blood tests to choose from that tested a smaller number of allergens. 2-ER-515–16. And for certain patients there was value in the comprehensive test. 6-ER-1735–36, 2-ER-508–17.

In March 2020, Arrayit started working on a test to detect Covid antibodies in blood samples. 6-ER-1698–99, 9-ER-2623. Given Schena's experience in creating other microarray blood tests, he was

confident that creating the Covid test would be the same process, applied to a new type of antibody. 3-ER-677, 8-ER-2006. The Arrayit test could only detect past exposure to Covid, and not necessarily an active Covid case, but there was medical value in patients knowing whether they had been exposed to the Covid virus in the past. 7-ER-1760, 7-ER-1904. Arrayit bundled the Covid test with its allergy test, so that patients received both tests even if they had concerns only about Covid. 6-ER-1585–91.

Arrayit's foray into Covid testing quickly brought the company to the attention of regulators, and various agencies began investigating the bundling of the Covid test with the allergy test, as well as Arrayit's communications with investors about the test. 7-ER-1994. Schena spoke with investigators in April and May 2020 and openly shared information with them. 7-ER-1996–2001, 7-ER-2046.

B. The charges and evidence at trial.

In June 2020, the government filed a complaint against Schena for healthcare and securities fraud. 10-ER-2691. The superseding indictment set forth the following charges, 2-ER-302–21:

- Count 1: conspiracy to commit healthcare and wire fraud in violation of 18 U.S.C. § 1349 based on multiple theories of alleged misconduct;
- Count 2: healthcare fraud in violation of 18 U.S.C. § 1347 based on the bundling of allergy testing with Covid testing for patient W.W. on May 1, 2020;
- Count 3: healthcare fraud based on the bundling of allergy testing with Covid testing for patient T.[R]. on May 13, 2020;
- Count 4: conspiracy to pay illegal kickbacks under 18 U.S.C. §§ 220(a)(2)(A) and 371, based on payments made to "induce a referral" of patients to Arrayit's lab in violation of the Eliminating Kickbacks in Recovery Act (EKRA);
- Count 5: paying an illegal kickback based on a commission payment to Marketer-1 (Mark Jablonski) on December 1, 2019, "in exchange for the referral of individuals to Arrayit";
- Count 6: paying an illegal kickback based on a commission payment to Marketer-1 (Mark Jablonski) on April 17, 2020, "in exchange for the referral of individuals to Arrayit";
- Count 7: securities fraud under 15 U.S.C. §§ 78j and 78ff, and 17 C.F.R. 240.10b-5 based on a press release on November 19, 2018, "about 'an allergy testing agreement' with multibillion-dollar company in Palo Alto, California";
- Count 8: securities fraud based on a tweet on August 8, 2019, about a "'$240,000,000 test kit manufacturing run'";
- Count 9: securities fraud based on emails to investors on March 19, 2020, "about demand for Arrayit's Covid-19 tests and coordination with government agencies."

Schena was tried on theories of direct liability, aiding and abetting, and co-conspirator liability. 1-ER-241–59.

i. Evidence of healthcare fraud (Counts 1–3).

The government charged Schena with conspiracy to commit healthcare fraud and two substantive counts of healthcare fraud. 2-ER-311–14. For the conspiracy count, the government offered several theories. 8-ER-2348–68.

One theory was the lack of medical necessity for Arrayit's testing practices. 3-ER-648, 7-ER-1819–20. The government put on evidence that, for the average patient, the 120-allergen test was medically unnecessary. *Id*. However, there was other evidence that the comprehensive test had useful applications, 6-ER-1692, and that physicians had other options to test for fewer allergens, if they thought a more targeted test made sense for the individual patient. 2-ER-515–16. The government also presented evidence that Arrayit bundled the Covid test with the allergy test regardless of whether patients needed or wanted them both. 9-ER-2354, 6-ER-1587–88. But Schena had explained that the allergy test helped Arrayit read the Covid tests. 6-ER-1708.

Another theory was that Arrayit lied in its applications to obtain the CLIA state licensing necessary to operate its lab and bill for testing. 8-ER-2348, 6-ER-1513–54, 2-ER-375–78. Schena could not meet the CLIA requirements for serving as lab director, so Arrayit hired a consulting physician, Julie Taguchi, to serve in that role. 5-ER-1215. Arrayit's compliance forms indicated that Taguchi was heavily involved in oversight of the lab operations and personnel, which was untrue because Taguchi only visited the lab every few months, signed paperwork, and did not perform any lab functions. 5-ER-1215, 6-ER-1660–73. However, the forms elsewhere indicated that Taguchi had delegated key duties to Schena, which was true. 6-ER-1515, 7-ER-1822.

Arrayit had trouble getting CLIA approval over concerns that Schena was performing the duties reserved for licensed physicians, 6-ER-1528, although Arrayit ultimately received approval, 6-ER-1554. According to the government, the purported misstatements about Taguchi's role in the CLIA application materials subsequently tainted all billing because, without CLIA approval, Arrayit could not bill insurance companies for its services. 8-ER-2348–9-ER-2353.

A third theory was that Arrayit "induced referrals" to its lab by paying its marketers illegal kickbacks. 9-ER-2366–67. This theory was related to the standalone kickback counts (Counts 4–6), addressed below. But, according to the government, the kickbacks also led to healthcare fraud because medical insurers have policies against kickbacks and would not have knowingly paid Arrayit for testing that was the product of kickbacks. *Id.*

Based on these different theories, the government asserted that Schena and others committed both healthcare and wire fraud by billing insurance companies for its testing (which was medically unnecessary and tainted by the CLIA issues and the kickbacks) and by using wires for the billing (by submitting forms and claims and receiving payments electronically). 8-ER-2343–9-ER-2367.

The two substantive counts of healthcare fraud related to the improper-bundling theory. 9-ER-2367–68. W.W. testified that she did not want an allergy test because she already knew that she had allergies and was concerned about the cost of the test. 6-ER-1585–91. However, the person who administered her Covid test gave her the impression that she had to agree to both. *Id.* She and her insurance

company were ultimately billed for both. *Id*. Similarly, T.R. testified that she thought she was only getting a Covid test, but her insurance company was later billed for an allergy test, too. 7-ER-1980–84.

The government put on evidence of other concerns with Arrayit's testing. These concerns included that Arrayit's allergy and Covid tests were not as accurate as advertised (*see, e.g.*, 3-ER-668, 3-ER-763, 7-ER-1935); that the tests were not processed as quickly as promised (*see, e.g.*, 3-ER-685–86); and that Arrayit misrepresented Taguchi's role in other regulatory submissions (*see* 6-ER-1676–77). However, the government did not ask the jury to find liability based on any of these concerns.

ii. Evidence of kickback violations (Counts 4–6).

Counts 4–6 charged Schena with conspiracy to pay illegal kickbacks under EKRA and two substantive counts of paying illegal kickbacks to marketer Mark Jablonski. 2-ER-314–16. Arrayit had a network of marketers, including Jablonski, who pitched medical practices and physicians on using Arrayit's allergy test and, once it was developed, Arrayit's Covid test. 10-ER-2662–64; 3-ER-678. These marketers were independent contractors, and some, like Jablonski, had other marketers working for them. 10-ER-2662–64, 3-ER-635–36.

In addition to Arrayit's test, marketers had several other products and services that they pitched to medical practices and physicians to provide a variety of solutions for patient care. 10-ER-2656, 10-ER-2662–64. Arrayit paid the marketers a commission based on the net profit that Arrayit made on every test that came from a medical practice or physician whom the marketer had pitched. *Id.*, 9-ER-2620–22, 3-ER-628.

Schena developed a sales pitch for marketers to use, which highlighted several reasons why physicians should test their patients for allergies using Arrayit's test. 9-ER-2627. According to the pitch, Arrayit's "blood testing offers significant advantages" over other skin or blood tests for allergies because it is "(1) fast (less than 5 minutes), (2) simple (can be performed at minute clinics, kiosks, at-home, etc.), (3) safe (no risk of anaphylaxis), (4) comfortable (no welts or skin irritation), (5) inclusive (infants, kids, special needs, seniors), (6) compatible with anti-histamines (many allergy patients take medicines that interfere with skin testing), (7) accurate (fewer false negatives and false positives than skin testing), (8) comprehensive (national panel includes 50 foods and 70 environmental), (9) affordable

(free test kits), (10) revenue growth (expanded patient volume and immunotherapy)." 9-ER-2627.

Arrayit provided marketers with a Client Services Manual that was given to the medical practices and physicians as part of the pitch for using Arrayit's test. 10-ER-2630–53; 3-ER-657, 3-ER-715–16. The manual described four simple steps for using the Arrayit allergy test kit: physicians and their patients fill out and sign an Arrayit requisition form to order the allergy testing; the patient's finger is pricked with the lancet provided in the kit; four drops of blood are placed on the Arrayit test card; and the medical practice mails the patient's blood sample card to Arrayit's lab for processing using the envelope and shipping label provided in the kit. 10-ER-2638. The manual also explained that any physician could sign up for the "Patient Data Solutions Portal" that "allows clinics to download test results, order test kits and shipping labels, and purchase immunotherapy products from [Arrayit's] therapeutics' partners." 10-ER-2639.

The Arrayit requisition form filled out by the physicians and their patients indicated that Arrayit was the "assigned testing laboratory" that would perform the testing, provide the results, and bill the

patient's insurance. 10-ER-2647. The form also stated that the referring physician would not receive any remuneration for using Arrayit's services and that there were other testing services available to the patient aside from Arrayit's. *Id.* Witness testimony confirmed that no physicians were paid by Arrayit or its marketers for using Arrayit's product or services. 3-ER-731, 3-ER-745.

Jablonski created supplemental marketing materials emphasizing that the Arrayit sample-collection kits would be provided "free of charge, easy to administer, [and] might lead to diagnosis of allergy that could open up potential for prescribing immunotherapy." 9-ER-2596, 3-ER-635. Jablonski emphasized this last point to show physicians that by detecting allergies in patients, they could potentially benefit from prescribing immunotherapy (and getting reimbursed for it) because, in his experience, "doctors will gravitate towards things that make more money" for their practices. 3-ER-650–51. Arrayit did not profit from the immunotherapy, which was offered by third parties. *Id.*, 3-ER-745.

Marketers would send Arrayit the names of the medical practices and physicians that they marketed to and helped register in the Arrayit portal. 5-ER-1449–6-ER-1451. Registering the practices or physicians

did not guarantee that they would actually use Arrayit for their patients; the physicians would decide whether to order testing. 5-ER-1449–6-ER-1451. As a result, marketers would sign up more practices and physicians than ended up using Arrayit's tests. *Id*. Marketers received periodic commission reports and payments based on the number of tests used by the practices that they pitched. 9-ER-2619. The two substantive kickback counts were based on commission payments to Jablonski in December 2019 and April 2020. 2-ER-316.

In a pre-trial motion to dismiss Counts 4–6, Schena argued that the commission payments to marketers did not constitute illegal kickbacks under EKRA because the marketers did not, and could not, decide to use Arrayit's test for any patients. 1-ER-260–62. The physicians made independent decisions about whether to use the test for their patients and never received payment from Arrayit or from the marketers for doing so. 3-ER-730–32, 3-ER-745, 9-ER-2619–22. The district court denied the motion and allowed the kickback theory to proceed to trial. 1-ER-262–66.

At trial, the government elicited testimony from two expert witnesses and three lay witnesses that EKRA prohibited labs from

paying marketers commissions and, according to the lay witnesses, prohibited Arrayit from hiring marketers as independent contractors. *See, e.g.*, 2-ER-397–401, 2-ER-491–92, 3-ER-637–39, 7-ER-1875–76, 5-ER-1223, 6-ER-1481. When defense counsel objected to this line of questioning, the district court allowed it, as long as it was framed in terms of the witnesses' experience or training. 2-ER-397–98. Further, while these legal conclusions were contrary to case law, defense counsel was prohibited from inquiring into that fact. 2-ER-454–55.

iii. Evidence of securities fraud (Counts 7–9).

At trial, the government put on extensive evidence about Arrayit's financial struggles, the personal loans taken out by the Schenas to help with funding, the company's failed attempts to produce audited financial reports, and weekly communications with investors through tweets, press releases, and emails, which often made their way onto investor message boards. *See, e.g.*, 3-ER-811, 4-ER-979, 5-ER-1196–97, 8-ER-2204–11. However, the jury was never asked to find liability based on this evidence. 2-ER-292–93. Instead, the securities fraud counts (Counts 7–9) focused on three specific alleged misstatements to investors and the general public. *Id.*

Count 7 concerned a press release on November 19, 2018, that announced that Arrayit had entered an "allergy testing agreement with Sutter Health." 2-ER-292, 10-ER-2684. The headline and other portions of the press release suggested a company-wide agreement with Sutter Health. 10-ER-2684. However, the second sentence of the press release explicitly stated that the allergy testing was being provided "via doctors in the Sutter Health-affiliated Palo Alto Medical Foundation" (PAMF). *Id*.

The evidence at trial showed that eight doctors at PAMF signed up to use Arrayit for some of their patients. 6-ER-1491. While various investors read the press release to mean that Arrayit had a deal with the entire Sutter organization, 4-ER-949–95, 5-ER-1340, an investor who testified at trial admitted that the sentence about the doctors at PAMF indicated that those doctors, in particular, would be using the Arrayit allergy test and not the whole Sutter Health organization. 4-ER-960–61.

Count 8 concerned a tweet on August 8, 2019, about a $240,000,000 test kit manufacturing run. 2-ER-292, 10-ER-2683. The government's witness who audited Arrayit's financial records stated

that he did not see any expenses that would reflect this large of a test kit run, but he admitted that he lacked any other information as to whether Arrayit conducted the run. 8-ER-2212–13, 8-ER-2253–56. Also, there was no evidence at trial as to how much it cost to run the kits.

In any event, the two shareholders who testified at trial about the test-kit-run tweet stated that while the announcement was important to them as investors, it did not influence them in relation to buying or selling the stock. 4-ER-949–53, 5-ER-1343–44. One investor stated that the test-kit-run announcement did not change his short-term investment decisions, 4-ER-953, 4-ER-961, and the other investor admitted that, even if she found out that it was false, she's not sure that she would have sold stock because of that. 5-ER-1343–44.

Count 9 concerned a batch of emails to investors on March 19, 2020, "about demand for Arrayit's Covid-19 tests and coordination with government agencies." 2-ER-293, 10-ER-2666–82. The emails stated, "Dear Valued Customer, We received more than 50,000 requests for our finger stick blood test for SARS-CoV2, the virus that causes coronavirus disease 2019 (COVID-19). Our team is coordinating with local, state

and federal agencies and with our distributors to make this test available to as many patients as possible on an expedited timeline. Please consult our website and press releases for updates." 10-ER-2666. According to the government, this statement was false because there was no evidence of 50,000 requests; the Covid test was not ready yet; the test did not have agency approval yet; and the test ultimately failed to receive agency approval. 8-ER-2335–38.

However, Schena's experience testing blood samples for other proteins (allergens) made him confident that the same microarray technology could detect Covid proteins (antibodies), 3-ER-677, 7-ER-2006. And before the emails in question were sent, Arrayit had ordered the antigens for its Covid test. 6-ER-1566–70. An email sent a few days later, from an Arrayit employee to an outside contact, included instructions and details about the Covid test and stated that Arrayit had "started building and soon hope[d] to offer" the test. 9-ER-2623. The email also included information that Schena had submitted to the Biomedical Advanced Research and Development Authority (BARDA), which is part of the U.S. Department of Health and Human Services. *Id.*

A few weeks after the emails, Arrayit submitted its application with the FDA for emergency use authorization for its test. 7-ER-1910. By FDA rules, Arrayit was allowed to offer its test prior to approval—and did not have to get approval at all—because the FDA did not require approval of serological Covid tests. 7-ER-1945, 7-ER-1963. Ultimately, the FDA did not grant approval of the test, but the FDA did not tell Arrayit to stop offering the test. 7-ER-1963.

C. Jury deliberations, verdict, and sentencing.

During two days of deliberations, the jury submitted several questions to the court. 2-ER-272–90. In particular, the jury focused on the mens rea definitions for Counts 1–6 versus Counts 7–9 and the definitions for "willfully" and "knowingly." 2-ER-279, 2-ER-283.

In what seems to be an undetected error, the instruction defining knowingly for Counts 1–6 contained the wrong version of the model jury instruction. 1-ER-255. The definition improperly included a sentence that must be omitted when the offense at issue requires the defendant's knowledge of unlawfulness. *Id.*; Addendum (Ninth Circuit Model Jury Instruction 4.8 (Knowingly)). The improper sentence stated: "The government is not required to prove that Mr. Schena knew that his acts

or omissions were unlawful." 1-ER-255. To the contrary, the government *did* have to prove knowledge of unlawfulness for Counts 1–6. 8-ER-2148. In fact, the instruction for willfully for Counts 1–6 correctly stated that "an act is done willfully if Mr. Schena acted with a bad purpose, that is, with general knowledge that his conduct was unlawful." 1-ER-254.

But due to the error, the willfully and knowingly instructions for Counts 1–6 directly conflicted: the willfully instruction required knowledge of unlawfulness and the knowingly instruction stated that no such knowledge was required. 1-ER-254–55. In response to the jury's question about how to reconcile the willfully and knowingly instructions, the court simply pointed the jury back to the instructions that contained the error. 2-ER-284. Neither the court, nor counsel for either party, appears to have noticed that the instruction for knowingly for Counts 1–6 contained the wrong version of the model instruction.

The remaining jury notes underscored that the jury was struggling with the instructions and its verdict. For instance, one question asked: "Should the entire jury instruction be interpreted literally exactly according to the dictionary with no regard to

commonsense or reasoning." 2-ER-288. Another question asked: "What should we do when a juror says, '. . . the judge's instructions are incorrect.'" 2-ER-281. Yet another question asked: "What are we to do if we feel we have reached a stalemate and feel we are now unable to move forward in a productive way?" 2-ER-281. At the end of its second full day of deliberations, the jury returned a verdict of guilty on all counts. 2-ER-291–93.

At sentencing, the court imposed 96 months on Counts 1–3 and 5–9, to be served concurrently, and 60 months on Count 4, to be served concurrently, for a total term of 96 months (8 years) in prison, followed by 3 years of supervised release. 1-ER-239; 1-ER-2–3.

The court also imposed nearly $25M in restitution as a discretionary condition of supervised release. 1-ER-7, 1-ER-239. The restitution order included $21,562,300.81 for losses to Arrayit shareholders, which the government based on the total equity accumulated by shareholders from 2015 (when the alleged securities fraud scheme was said to have begun) to April 2020 (when the SEC suspended trading for two days)—with all of that equity being presumed worthless after the suspension. 2-ER-268–71, 1-ER-19–22.

The district court had rejected this very same estimate for purposes of calculating loss for the sentencing guidelines because of the overbroad scope and the unjustified methodology used by the government. 1-ER-19–22. In terms of breadth, the securities fraud convictions arose from three specific misstatements at three specific times, and the government made no attempt to isolate the effect of those misstatements on the value of the shares. 1-ER-20. Instead, the government assumed that investors lost everything they invested over a five-year period, which was far beyond the scope of offense conduct. *Id.* Further, the government's estimate assumed, without any evidence, that the shares became worthless after the brief trading suspension. *Id.*

The restitution order also included $2,727,240.14 in losses to insurance companies, based on all reimbursements paid to Arrayit for its testing services. 1-ER-7–8. But, here, too, the district court had rejected this estimate for calculating loss at sentencing because the government failed to substantiate that all of the testing was worthless. 1-ER-22–29. Nonetheless, the court allowed the estimate for purposes of restitution and forfeiture. 1-ER-7–8.

SUMMARY OF THE ARGUMENT

I. As a matter of law, Arrayit's commission payments to marketers do not qualify as illegal kickbacks to induce referrals under EKRA because the non-physician marketers did not, and could not, refer any patients to Arrayit's lab and, thus, were compensated for their marketing efforts and not for corruptly referring patients to Arrayit in return for compensation, as the Fifth Circuit held in *United States v. Miles*, 360 F.3d 472, 479–81 (5th Cir. 2004).

II. Alternatively, the district court abused its discretion by admitting witness testimony expressing legal conclusions about the application of EKRA to marketer payments because such testimony violated the well-settled rule that the judge provides the relevant law, and the jury applies the law—and neither role can be usurped by witnesses. *Nationwide Transp. Fin. v. Cass Info. Sys.*, 523 F.3d 1051, 1058–60 (9th Cir. 2008).

III. Further, the district court prejudicially erred by giving the wrong jury instruction to define knowingly for Counts 1–6, because it negated the knowledge-of-unlawfulness requirement for the offenses, and a properly instructed jury might not have been convinced, beyond a

reasonable doubt, that Schena knew his conduct was unlawful. *See United States v. Liu*, 731 F.3d 982, 988–92 (9th Cir. 2013).

IV. The evidence is insufficient for the securities fraud counts because the three specific statements at issue, taken in context and at the time they were issued, do not contain material misstatements of fact. *See Zenoff v. Sorrento Therapeutics, Inc. (In re Sorrento)*, 97 F.4th 634, 641–42 (9th Cir. 2024).

V. The district court erred by imposing restitution and forfeiture for losses that resulted from conduct outside the specific acts for which the jury found Schena guilty, because restitution and forfeiture must be limited to "'the loss caused by the specific conduct that is the basis of the offense of conviction.'" *United States v. Batson*, 608 F.3d 630, 636–37 (9th Cir. 2010) (citation omitted) (restitution); *see also* 18 U.S.C. § 982(a)(7) (similar standard for forfeiture).

STANDARDS OF REVIEW

The Court reviews de novo whether a "theory of [liability] at trial was legally valid," *United States v. Milheiser*, 98 F.4th 935, 941 (9th Cir. 2024), and whether the jury instructions correctly stated the law, *United States v. Cortes*, 732 F.3d 1078, 1084 (9th Cir. 2013).

Evidentiary rulings are reviewed for an abuse of discretion, and unpreserved errors are reviewed for plain error. *United States v. Preston*, 873 F.3d 829, 835 (9th Cir. 2017). "'The legality of an order of restitution is reviewed de novo[,]'" and, if "'it is within the bounds of the statutory framework,'" it is reviewed for an abuse of discretion. *United States v. Rodrigues*, 229 F.3d 842, 844 (9th Cir. 2000) (citation omitted).

ARGUMENT

I. As a Matter of Law, Arrayit's Payments to Marketers Do Not Qualify as Illegal Kickbacks to Induce Referrals Under EKRA (Counts 4–6).

According to the government's theory, Arrayit paid marketers illegal kickbacks in "exchange for the referral of patients to Arrayit," 1-ER-2377, even though the physicians to whom they marketed—not the marketers—made the decision of whether to refer patients to Arrayit and handled the referral and testing process with their own patients. Throughout the proceedings, Schena maintained that Arrayit's payments to marketers did not constitute illegal kickbacks. Schena's interpretation is correct because the ordinary meaning and context of the EKRA kickback provision limits its reach to payments made to someone with the power to refer a patient to a lab, in exchange for the

referral. EKRA does not criminalize commissions to marketers for successfully pitching physicians to use a particular lab.

A. The common meaning of kickback compels this reading.

EKRA prohibits both sides of a kickback: the payor and the recipient. 18 U.S.C. § 220(a)(1), (2). Specifically, it penalizes anyone who pays "remuneration (including any kickback, bribe, or rebate) . . . to induce a referral" of a patient to a lab (§ 220(a)(2)(A)), as well as anyone who "solicits or receives any remuneration . . . in return for referring a patient" to a lab (§ 220(a)(1)). Because "remuneration," "kickback," "bribe," and "rebate" are not defined by statute, they are given their ordinary meaning. *See* 18 U.S.C. §§ 202, 220(e) (defining other statutory terms but not the terms in question); *Dubin v. United States*, 599 U.S. 110, 118 (2023) (explaining that statutory terms are defined by their """ordinary or natural meaning""" (citation omitted)). Further, the meaning of the EKRA provision as a whole comes from reading the words of the provision together in their "[l]inguistic and statutory context" and not from "the broadest imaginable definitions of [the] component words." *Dubin*, 599 U.S. at 120 (quotation marks and citations omitted).

The words kickback, bribe, and rebate are commonly and interchangeably used to indicate a payment "bestowed or promised with a view to pervert the judgment or corrupt the conduct" of the recipient, in return for "a gain corruptly secured." *United States v. Rodrigues*, 159 F.3d 439, 450 (9th Cir. 1998) (explaining what the government had to prove for a kickback or a bribe); *see also United States v. Kats*, 871 F.2d 105, 108 n.2 (9th Cir. 1989) (per curiam) (defining a kickback as "a payment for granting assistance to one in a position to control a source of income, unless such payment is wholly and not incidentally attributable to the delivery of goods or services"). All of these terms refer to "a corrupt payoff" or "a bribe." *Rodrigues*, 159 F.3d at 450.

This common understanding of a kickback as a corrupt payoff is reflected in the EKRA provisions, which, read together, prohibit payments that corruptly compensate someone "in return for referring a patient." 18 U.S.C. § 220(a)(1), (2)(A). Implicit in this arrangement is that the recipient of the kickback has the ability to make (or decide not to make) the referral and is tainted in making that decision because of the influence of the payment.

Here, the marketers did not have the ability to make referrals. 3-ER-730–32, 3-ER-745. Instead, they pitched medical practices and physicians on making referrals. *Id.*, 9-ER-2596–2618, 10-ER-2630–53. If a physician ultimately decided to use Arrayit's test for a patient, the marketer who pitched that practice received a commission. 3-ER-730–32, 9-ER-2620–22. Neither the marketers nor Arrayit compensated physicians or their practices for using Arrayit's test. 3-ER-731.

Thus, the marketers could only exercise whatever power of persuasion they had through their marketing. 3-ER-731–32; 6-ER-1449–7-ER-1451. And marketing efforts in the medical field are not inherently unlawful or corrupt. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557–58, 567–73 (2011). They are protected commercial speech. *Id.*

The government's theory improperly converts commission payments for successful marketing into a novel form of kickbacks. And because the commission payments "bear[] little relationship to the common understanding of" kickbacks, *Dubin*, 599 U.S. at 120, those payments simply cannot support a conviction under EKRA. *See id.* (rejecting the government's theory that the commission of healthcare fraud also constituted aggravated identity theft because it stretched the

theft statute beyond its ordinary meaning); *see also United States v. Choy*, 309 F.3d 602, 606 (9th Cir. 2002) (rejecting the government's theory of bribery because it interpreted the statute too "loosely").

B. Other courts and the OIG use this reading.

The Fifth Circuit is the only Court of Appeal to directly address this type of marketing-based kickback theory and soundly rejected it in *Miles*, 360 F.3d at 479–81. As here, the government's case "rested on evidence" that marketers were compensated for successfully marketing the defendant's healthcare services. *Id.* at 479. In *Miles*, the defendants' company, APRO, paid marketers to distribute information about their services to physicians, and "[w]hen a physician determined that home health care services were needed for a patient, the physician's office might contact [the marketer], who would then furnish APRO with the patient's name and Medicare number for billing purposes." *Id.* APRO paid marketers a commission for each patient who came to APRO "as a result of [the marketers'] efforts." *Id.*

The Fifth Circuit ruled that the commission payments were not illegal kickbacks "because [the marketers] never actually referred anyone to APRO, but simply engaged in advertising activities on behalf

of APRO"; physicians independently decided whether to refer patients. *Miles*, 360 F.3d at 480. "The payments from APRO to [the marketers] were not made to the relevant decisionmaker as an inducement or kickback for sending patients to APRO." *Id.*

The Fifth Circuit distinguished situations in which marketers or sales reps have their own control or authority over patient referrals. *Miles*, 360 F.3d at 480. For example, in *United States v. Polin*, 194 F.3d 863, 864–65 (7th Cir. 1999), a pacemaker sales rep had the power to select which monitoring service to use after a physician ordered monitoring for a patient. The commissions that the sales rep in *Polin* received for signing up patients with the defendant's monitoring service were therefore illegal kickbacks because they were in return for the rep using his authority to refer patients to the defendant. *Id.* at 865.

In a subsequent case, the Fifth Circuit articulated the following test from *Miles* to distinguish a kickback in the marketing context: "Where advertising facilitates an independent decision to purchase a healthcare good or service, and where there is no evidence that the advertiser 'unduly influence[s]' or 'act[s] on behalf of' the purchaser, the mere fact that the good or service provider compensates the advertiser

following each purchase is insufficient to support the provider's conviction for making a payment 'to refer an individual.'" *United States v. Shoemaker*, 746 F.3d 614, 628 (5th Cir. 2014) (citations omitted). And although *Miles* involved the Anti-Kickback Statute (42 U.S.C. § 1320a-7b (AKS)), its analysis is directly applicable to EKRA, which shares almost identical language and structure. *Compare* § 1320a-7b(1)-(2) *with* 18 U.S.C. § 220(a) (1)-(2); *and see* 164 Cong. Rec. S6467-02, S6473 (modeling EKRA on AKS).

Indeed, the same distinction that *Miles* drew was applied to EKRA by the district court in *S&G Labs Haw., LLC v. Graves*, No. 19-00310, 2021 U.S. Dist. Lexis 200365, *32–34 (D. Haw. Oct. 18, 2021). S&G's lab performed urinalysis, and S&G compensated its marketers on a per-test basis for every test ordered by a physician or counseling center that the marketers pitched to use S&G's services. *Id.* The court recognized that while, "[u]ndoubtedly, [the] commission-based compensation structure induced [marketers] to try to bring more business to S&G," the marketers did not control the independent decision of whether the tests were sent to S&G's lab. *Id.* at *33–34. Thus, the compensation was not an illegal kickback to induce referrals in violation of EKRA. *Id.*

The analysis in *Miles* and *S&G* aligns with the position taken by the Office of the Investigator General. According to the OIG, "[a]n important aspect of inducement is that the remuneration be directed towards an individual or entity 'in a position to generate . . . health care program business,'" and that the remuneration "could reasonably induce the person or entity to refer such [business]." *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 401 (6th Cir. 2015) (quoting OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005) and concluding that plaintiff failed to allege a valid kickback theory); *see also Guilfoile v. Shields*, 913 F.3d 178, 188–189 (1st Cir. 2019) (quoting same and concluding that plaintiff alleged a valid kickback theory that involved "the use of payments to improperly influence decisions on the provision of health care").

Thus, the AKS, and by extension EKRA, "'contemplate[s] that the person receiving the inducement is the one prohibited from making the referral to the entity that offered the remuneration.'" *Jones-McNamara*, 630 F. App'x at 401 (citation omitted). That did not occur here. Arrayit paid the marketers commissions—but the marketers could not and did not make referrals. And no one paid the physicians—

who independently decided whether to make the referrals.

C. This restrained reading is required in criminal law.

Thus, properly interpreted, EKRA does not criminalize payments to marketers who have no power to make referrals. This "targeted reading accurately captures the ordinary understanding" of a kickback, *Dubin*, 599 U.S. at 120, and accords with the restraint that courts must exercise "'in assessing the reach of a federal criminal statute,'" *id.* at 129 (citation omitted), including where, as here, the statute also has civil liability attached, *Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004).

"This restraint arises 'both out of deference to the prerogatives of Congress and out of concern that a fair warning should be given to the world in language that the common world will understan[d] of what the law intends to do if a certain line is passed.'" *Dubin*, 599 U.S. at 129 (citation omitted). "After all, '[c]rimes are supposed to be defined by the legislature, not by clever prosecutors riffing on equivocal language.'" *Id.* at 129–30 (citation omitted); *see also Skilling v. United States*, 561 U.S. 358, 410–11 (2010) (rejecting the government's reading of the fraud statute as contrary to the rule of lenity and concluding that "honest-services fraud does not encompass conduct more wide ranging than the

paradigmatic cases of bribes and kickbacks"). Here, the government's reading of the statute violates this principle of restraint.

D. No other kickback theories were charged or proven.

In its rebuttal closing argument at trial, the government offered two new twists on the kickback theory, but neither can support the conviction. *See* 9-ER-2479–80.

First, the government referenced an isolated statement of cooperating witness Mark Jablonski that marketers "controlled" the blood samples. 9-ER-2480. Taken in its proper context, this vague statement about control was a boastful reference to his successful marketing of Arrayit's test over its competitors' tests and the fact that, if he did not like Arrayit's compensation deal, he could stop marketing Arrayit's test and, in his view, the use of Arrayit's test would decrease as a result.

Yet the power of persuasion that Jablonski and other marketers created through their marketing pitches does not equate to "'unduly influenc[ing]' or 'act[ing] on behalf of' the purchaser.'" *Shoemaker*, 746 F.3d at 628. The effect of marketing in our everyday lives makes this point. We are inundated with persuasive ads, salespeople, and

marketers that influence our decisions to buy certain products, or use certain services, but we would never say that the advertisers control our independent decision making, unduly influence us, or act on our behalf. Likewise, Arrayit's marketers did not control referrals through their persuasive efforts.

In any event, the remainder of Jablonski's testimony and his own marketing materials make clear that he did not control patient blood samples. He had no contact with patients; he could not fill out a requisition form to order a blood test because he is not a physician; he had no role in physicians' independent decisions of whether to use Arrayit's test for their patients; and the physicians who decided to use Arrayit's test handled the whole process themselves: the physicians took the blood samples with the lancet and card provided in Arrayit's kit and sent the sample to Arrayit's lab with the envelope provided. 3-ER-730–32, 3-ER-745, 9-ER-2608–13, 10-ER-2638–39, 6-ER-1726–30. Further, because Arrayit's microarray technology is unique in its ability to test very small amounts of blood, other labs could not process the samples once they were taken. *See* 10-ER-2644.

In sum, Jablonski's comment was "simply too vague to establish a reliable evidentiary basis" for the theory that Arrayit's marketers' directly controlled patient blood samples or referrals. *United States v. Culps*, 300 F.3d 1069, 1081 (9th Cir. 2002) (concluding that testimony was too vague to support government's factual theory). Further, the new theory of control was at odds with the factual basis for Jablonski's own prosecution for kickbacks; that prosecution was based on his compensation for marketing to physicians, not for any personal control over blood samples or referrals. *See United States v. Jablonski*, No. 21-cr-00213-EJD, Dkts. 16, 30, 33 (N.D. Cal.).

Second, the government referenced supposed "kickbacks" to physicians Julie Taguchi and Madan Mohan, without explaining this theory any further. 9-ER-2480. The government made no effort to tie these supposed direct-to-physician kickbacks to the marketer-kickback theory alleged in the indictment, or to the specific marketer kickbacks alleged in Counts 5 and 6: payments *to Jablonski* in December 2019 and April 2020. 2-ER-314–16, 2-ER-292. Thus, this reference was "simply too vague" to support the conviction, *Culps*, 300 F.3d at 1081, and impermissibly depended on "a set of facts distinctly different from that

set forth in the indictment." *Choy*, 309 F.3d at 607 (reversing conviction due to a fatal variance with allegations in the indictment).

Accordingly, Arrayit's payments to marketers, and to Jablonski specifically, were not illegal kickbacks under EKRA. Schena's conviction for conspiring to pay unlawful kickbacks (Count 4) and for paying unlawful kickbacks (Counts 5 and 6) must be reversed.

II. Alternatively, the District Court Abused its Discretion by Admitting Testimony Expressing Legal Conclusions About the Application of EKRA to Marketer Payments.

If the Court does not reverse the EKRA counts based on the invalidity of the government's legal theory, then it must reverse the counts based on the improper admission of witness testimony offering the legal conclusion that payments to marketers constitute illegal kickbacks under EKRA.

"The problem with testimony containing a legal conclusion is in conveying the witness' [view of the] legal standards to the jury"—which might well be incorrect. *United States v. Zipkin*, 729 F.2d 384, 386–87 (6th Cir. 1984) (admission of legal testimony was reversible error); *see also Nationwide*, 523 F.3d at 1058–59 (exclusion of legal testimony was proper); *United States v. Poschwatta*, 829 F.2d 1477, 1483 (9th Cir.

1987) (same). Legal conclusions from witnesses "invade[] the province of the trial judge." *Nationwide*, 523 F.3d at 1059. Further, legal conclusions often "'do nothing more than tell the jury what result it should reach.'" *Nationwide*, 523 F.3d at 1060 (citation omitted). Thus, the district court should have excluded the testimony containing legal conclusions.

A. Legal testimony of expert Stephen Quindoza.

The first interpretation of EKRA at trial came from Stephen Quindoza, a government expert who investigates suspected healthcare fraud. 2-ER-359–60. Before trial, defense counsel objected that Quindoza's proposed testimony might include legal conclusions and any such testimony should be excluded. 2-ER-300–01. The government assured the court that it would not elicit such testimony. 2-ER-294–95.

In front of the jury, however, the government asked Quindoza about the types of payments that constitute illegal kickback under EKRA and AKS. 2-ER-397–98. As soon as this line of questioning began, defense counsel objected that it called for a legal conclusion. *Id.* The district court permitted the testimony as long as it was phrased in terms of Quindoza's "training." *Id.*

The government elicited that the type of kickback prohibited under EKRA "include[s] a laboratory payment to a marketer for the purposes of referring them patient's medical testing to the laboratory." 2-ER-400. The government also elicited that it would violate EKRA if a lab "was paying kickbacks in the form of a percentage of . . . reimbursements to marketers in exchange for inducing a referral." 2-ER-401–02.

On cross-examination, defense counsel was prevented from exposing Quindoza's lack of qualifications to draw these legal conclusions. 2-ER-454–55. Defense counsel asked Quindoza whether his understanding of EKRA was based on information provided to him by someone else. 2-ER-454. Quindoza asserted that his legal conclusions were based on his training, "look[ing] at the statute itself, and written guidance provided by Medicare and Medicaid services." *Id*. Defense counsel followed up by asking whether Quindoza had encountered any sources that interpreted EKRA differently, and when Quindoza responded, "no," counsel inquired whether Quindoza knew "one way or the other if there are [court] opinions contrary to yours." The district court sustained an objection. 2-ER-454–55.

Having successfully cut off defense counsel's questioning about the authorities Quindoza consulted for his interpretation, the government elicited that Quindoza relied upon "searchable databases that I have access to, as well as the specific training that I have through health training conferences in recent years." 2-ER-464. The government asked, "And if you know, does EKRA's view of kickbacks include that kickbacks would be laboratory payments to marketers for referring patient services to the laboratory?" 2-ER-465. Quindoza responded, "Yes, it does." *Id.*

Quindoza's testimony thus contained legal conclusions about EKRA's application to payments to marketers. The fact that Quindoza's interpretation was based on his "training," 2-ER-398, did not render it non-legal. Rather, the application of a statute to a set of facts is ultimately a legal question. *Svela v. Union Oil Co.*, 807 F.2d 1494, 1498 (9th Cir. 1987). Accordingly, the district court abused its discretion in admitting the testimony.

In addition, the district court abused its discretion by precluding defense counsel from exploring the shortcomings in Quindoza's legal knowledge after allowing the prosecution to inquire into Quindoza's

qualifications for interpreting EKRA. Cross-examination can inquire into all "matters embraced within the direct examination." *Lewis v. United States*, 373 F.2d 576, 578 (9th Cir. 1967). Defense counsel was entitled to explore whether Quindoza had consulted court cases in forming his opinion, because consulting case law is a typical part of determining the meaning of a statute. *See* 3-ER-595.

Where, as here, improper testimony has been admitted, the Court "begin[s] with a presumption of prejudice," and the government must show that "'it is more probable than not that the jury would have reached the same verdict'" without the testimony. *United States v. Wells*, 879 F.3d 900, 923–24 (9th Cir. 2018). Here, the government cannot meet that burden. Schena's defense was that the payments to marketers did not actually induce referrals and, thus, did not violate EKRA. *See* 9-ER-2441–42. But Quindoza's testimony gutted this defense by declaring that payments to marketers *do* induce referrals for purposes of violating EKRA.

Not surprisingly, the government invoked Quindoza's testimony in closing argument. 9-ER-2366. And the jury was likely to credit Quindoza's testimony, given his purported expertise on EKRA and AKS,

as well as the "aura of special reliability and trustworthiness" that comes from being declared an expert witness. *United States v. Amaral*, 488 F.2d 1148, 1152 (9th Cir. 1973).

Thus, Quindoza's authoritative testimony that EKRA criminalizes payments to marketers, taken alone, is enough to have affected the jury's verdict. Even more so, the cumulative prejudice of similar testimony from other witnesses requires reversal, as discussed below.

B. Legal testimony of expert Alex Kondratenko.

Having succeeded in eliciting legal opinions from Quindoza, the government elicited similar testimony from Alex Kondratenko, a fraud investigator who testified as an expert. 7-ER-1864–66, 7-ER-1875–76. The government elicited from Kondratenko that he was "well informed on kickbacks" and "laws related to it"; that "a lab payment to a marketer in exchange for the marketer referring patients to the lab [would] qualify as a kickback"; and that "a lab [that] paid marketers a percentage of [the insurance] reimbursement in exchange for referred services . . . would . . . be considered a kickback." 7-ER-1875–76.

While the defense did not object to this testimony, it was not required to do so because the district court's prior ruling allowing

Quindoza's testimony over objections "left no possibility of a different ruling." *United States v. Varela-Rivera*, 279 F.3d 1174, 1177–78 (9th Cir. 2002) ("there is no requirement that a party engage in a futile and formalistic ritual to preserve the issue"). In any event, admitting the testimony constitutes an error that is plain because "[i]t is well settled" that witnesses cannot give legal opinions. *United States v. Brodie*, 858 F.2d 492, 496–97 (9th Cir. 1988), *overruled on other grounds by United States v. Morales*, 108 F.3d 1031, 1033 (9th Cir. 1997) (en banc).

Further, for the reasons already discussed above with regard to Quindoza's testimony, Kondratenko's testimony resulted in prejudice because it gutted Schena's defense that the payments to marketers did not improperly induce referrals under EKRA. Even more so, the cumulative effect of all the improper testimony requires reversal under whatever standard of review is applied.

C. Legal testimony of lay witnesses.

Along similar lines, the government repeatedly elicited legal conclusions from lay witnesses that EKRA required sales reps to be paid as employees rather than as independent contractors and

prohibited commissions or percentage-of-sales payments. 2-ER-476–77, 2-ER-488–93, 3-ER-637–41, 5-ER-1223–26, 6-ER-1481–84.

For example, cooperating witness Paul Haje testified that after EKRA's passage it was "100 percent clear" to him that labs "couldn't pay marketers a percentage of the reimbursement anymore." 6-ER-1481, 5-ER-1223. Haje also repeatedly referred to the payments to marketers as "kickbacks." 5-ER-1213, 5-ER-1222, 6-ER-1483. Jablonski, another cooperating witness, testified that after EKRA's passage "all of these labs had to switch how they were paying their employees from a 1099 to a W-2." 3-ER-638. Another witness, Matt Atwood opined, "The new EKRA laws said that you can't reimburse sales reps if they're not a W-2 employee." 2-ER-491.

The context for this classification-based payment theory was never explained at trial, but it seems to arise from a provision in EKRA that exempts payments made "to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) . . ., if the . . . payment . . . does not vary" based on the number of referrals. 18 U.S.C. § 220(b)(2). However, there was no need for Arrayit's payment structure to meet this exemption if EKRA did not

apply to the marketers in the first place, as Schena maintained. *See S&G*, 2021 U.S. Dist. Lexis 200365 at *34–35 ("The exception is only relevant if there is a violation of the provisions of [EKRA] in the first instance.").

This testimony from lay witnesses about their own understanding of EKRA and its employment-classification requirements should not have been admitted. Defense counsel objected to some, but not all, instances of this questioning and any lapses should be excused because the district court had made it clear that it would allow legal conclusions as long as they were based on the witnesses' own "understanding" or "training." *See* 2-ER-397–98, 3-ER-641; *Varela-Rivera*, 279 F.3d at 1177–78 (no requirement to object where it would be futile).

Even if plain error review is applied where counsel failed to object, the error in admitting this testimony is plain because the legal conclusions were improper. *Brodie*, 858 F.2d at 496. Further, the cumulative prejudice from the testimony warrants reversal under the harmless or plain error standard, as explained below.

D. Cumulative prejudice from all legal testimony.

Where, as here, there are multiple instances of improper testimony, "a balkanized . . . review is far less effective than analyzing the overall effect of the errors in the context of the evidence introduced at trial against the defendant." *Preston*, 873 F.3d at 835 (quotation marks and citations omitted). "In deciding whether the combined effect of multiple errors prejudiced a defendant we ask whether the errors stand in unique symmetry . . . , such that [they] amplify each other in relation to a key contested issue in the case." *Id*. (quotation marks and citations omitted). "In addressing [the] cumulative prejudicial error," the Court "consider[s] all errors," whether "preserved for appeal with a proper objection or which were plain error." *United States v. Berry*, 627 F.2d 193, 200–201 (9th Cir. 1980).

The improper legal conclusions from several government witnesses about the application of EKRA to marketer payments amplified each other on a key contested issue and, thus, almost certainly affected the jury's decision-making. Schena did not dispute the payment structure for Arrayit's marketers, or that the payments were made. Instead, he disputed that the payments violated EKRA. 9-

ER-2441–42. *Even if* the government was right that EKRA applied to marketers, it could not prove its case by eliciting legal conclusions from its witnesses, which usurped the role of the judge and jury. *Nationwide*, 523 F.3d at 1059–60; *Brodie*, 858 F.2d at 496–97. Accordingly, the EKRA counts (Counts 4–6) must be reversed.

III. Further, the District Court Erred by Giving the Wrong Jury Instruction to Define "Knowingly" for Counts 1–6, Which Negated the Knowledge-of-Unlawfulness Element.

Separately, Counts 1–6 must be reversed because the jury received the wrong instruction for knowingly, which stated that the government *was not required* to prove that Schena knew his acts were unlawful, when the government *was required* to prove such knowledge. The government cannot establish that this error was harmless because the improper instruction negated a mens rea requirement; the jury was confused by the instruction; and a properly instructed jury might have reached a different result, based on a reasonable doubt as to whether Schena knew his acts were unlawful.

A. The court used the wrong version.

Healthcare fraud offenses, as alleged in Counts 1–3, require that the defendant acted "knowingly and willfully" in executing a scheme to

defraud. 18 U.S.C. § 1347(a) ("Whoever knowingly and willfully . . ."). Likewise, EKRA offenses, as alleged in Counts 4–6, require that the defendant acted "knowingly and willfully" in paying a kickback. 18 U.S.C. § 220(a) ("whoever . . . knowingly and willfully . . .").

Generally, the term knowingly requires proof that the defendant knew "of the facts that constitute the offense," but does not require proof that the defendant knew the conduct was unlawful. *Bryan v. United States*, 524 U.S. 184, 193 (1998). For the term willfully, however, "[t]he jury must [generally] find that the defendant acted with . . . knowledge that his conduct was unlawful." *Id.* Thus, when an offense must be committed both knowingly and willfully, the definition for knowingly must be tailored so as not to cancel out the knowledge-of-unlawfulness requirement for willfully.

The model jury instruction for knowingly reflects this need for tailoring. It contains a standard definition with a bracketed sentence that courts include or omit based on the knowledge requirement:

> An act is done knowingly if the defendant is aware of the act and does not [act] [fail to act] through ignorance, mistake, or accident. [*The government is not required to prove that the defendant knew that [his] [her] acts or omissions were unlawful.*] You may consider evidence of the defendant's

> words, acts, or omissions, along with all the other evidence, in deciding whether the defendant acted knowingly.

Addendum (Ninth Circuit Model Jury Instruction 4.8 (Knowingly) (emphasis added)). The comments to the instruction make clear that the bracketed sentence "should not be given when an element of the offense requires the government to prove that the defendant knew that what the defendant did was unlawful." *Id.*

Because Schena's healthcare fraud and EKRA counts required knowledge of unlawfulness, Schena's proposed jury instruction for the definition of "knowingly" correctly omitted the bracketed sentence. 2-ER-298–99. The government's version, however, included the bracketed sentence. 2-ER-296–97. At the charge conference, the district court acknowledged that Schena had to know that his acts were unlawful for Counts 1–6 and indicated that it would follow the model instruction to define knowingly. 8-ER-2148, 8-ER-2127–30.

The court also acknowledged a possible source of confusion for the jury: the definitions of willfully and knowingly were different for the healthcare fraud and EKRA counts (Counts 1–6) than they were for the securities fraud counts (Counts 7–9). 8-ER-2127–30, 8-ER-2141.

Specifically, while Counts 1–6 required knowledge that the conduct was unlawful, Counts 7–9 required knowledge that the statements were untrue, but not that making them was unlawful. *Id.*; *United States v. Tarallo*, 380 F.3d 1174, 1188 (9th Cir. 2004) (defining willfully for securities fraud). Thus, the definitions for willfully and knowingly had to be adjusted accordingly. The court noted that these differing definitions should be kept "as close as possible to the counts they're relevant to." 8-ER-2128.

Despite the court's best effort to keep the definitions straight, the instructions given to the jury used the wrong version of knowingly for Counts 1–6 by including the bracketed sentence. 1-ER-255. This mistake caused a direct conflict between the willfully instruction, which stated that Schena *had to know* his conduct was unlawful 1-ER-254, and the knowingly instruction, which stated that he *did not have to know* it was unlawful. 1-ER-255.

During deliberations, the jury expressed confusion about the definitions for willfully and knowingly. 2-ER-279–84. In one question the jury asked for "further clarification on the meaning of 'willfully' . . . and if/how the meaning is different for counts 1–6 and 7–9." 2-ER-279.

In another question, the jury cited the mistaken instruction and asked, "does 'willful' include 'knowing'" and "[i]s it possible to be 'willful' but not knowing." 2-ER-283. In response, the court pointed them back to the jury instructions that contained the error. 2-ER-279–84.

B. The error requires reversal.

The standard for reversal depends on whether defense counsel sufficiently preserved an objection to the erroneous instruction. If so, the Court applies the harmless error standard, and the government must demonstrate that "it is clear beyond a reasonable doubt that a rational jury would have found the defendant guilty absent the error." *Liu*, 731 F.3d at 992 (quotation marks and citations omitted). If not, "there must be (1) error, (2) that is plain, . . . (3) that affect[s] substantial rights, [and] (4) [that] seriously affect[s] the fairness, integrity, or public reputation of judicial proceedings." *United States v. Bear*, 439 F.3d 565, 568 (9th Cir. 2006) (quotation marks and citations omitted). Under either standard, reversal is required because the plainly erroneous version of the knowingly instruction negated the government's duty to prove knowledge of unlawfulness and a properly instructed jury might not have found that such knowledge existed.

As an initial matter, defense counsel sufficiently preserved the issue for review. Defense counsel offered the correct version of knowingly, and, at the charge conference, the district court indicated that it would give the correct version. 8-ER-2129. It is unclear when the court provided counsel with the final instructions and whether the court solicited any objections, given that the parties had already settled on the instructions at the charge conference. Accordingly, counsel should be excused for failure to object to an undetected clerical error that was at odds with the court's oral explanation on how it would instruct the jury. *See*, *e.g.*, *Liu*, 731 F.3d at 987–88 (recognizing that failure to object may be excused in certain circumstances).

Still, under either standard, the error was prejudicial because the instruction for knowingly negated the government's duty to prove Schena's knowledge of unlawfulness. And although the willfully instruction for Counts 1–6 correctly stated the law—that the government did have to prove Schena's knowledge of unlawfulness—this contradictory instruction did not cure the error. "[E]rroneous instructions are not cured by correct instruction in other portions of the

main charge because the jury may be misled." *Seltzer v. Chesley*, 512 F.2d 1030, 1035 (9th Cir. 1975).

Further, "[n]othing in" the instructions here "makes clear to the jury that one of the[] contradictory instructions carries more weight than the other." *Francis v. Franklin*, 471 U.S. 307, 322 (1985). Thus, there is "no way of knowing which of the two irreconcilable instructions the jurors applied in reaching their verdict." *Id.* "A reasonable juror could easily have resolved the contradiction," *id.*, by assuming that the willingly instruction was wrong, instead of realizing that the knowingly instruction was wrong.

Notably, all the other instructions for knowingly and willfully in this case explicitly stated that knowledge of unlawfulness *was not* required for conviction. 1-ER-255–57. Thus, a reasonable juror could assume that the majority rule from the instructions—requiring no knowledge of unlawfulness—was the correct legal standard. Further, a reasonable juror could also assume that the *knowingly* instruction governs over the willfully instruction when it comes to what *knowledge* is required for the offense. The law's use of the term willfully to define the knowledge requirement is counterintuitive.

Moreover, the district court's responses to the jury's questions, which showed that they were confused about the willfully and knowingly instructions, simply pointed them back to the instructions that confused them in the first place. 2-ER-284. This response "provided no guidance on the pivotal question." *Deck v. Jenkins*, 814 F.3d 954, 986 (9th Cir. 2016).

The uncorrected error prejudiced Schena because a properly instructed jury could have found that the government failed to prove, beyond a reasonable doubt, that Schena knew his conduct was unlawful. While the government painted the picture of Schena as the mastermind of a massive fraud scheme who flouted the law to grow the company, 8-ER-2317–9-ER-2360, the evidence supported the defense's counter-narrative that Schena was a smart scientist with little experience in the administrative and regulatory aspects of running Arrayit, who made business missteps along the way but never intended to perpetrate fraud or illegal kickbacks. 9-ER-2381–86.

The jury's deliberations for two days suggest that this was a close case, and the jury's questions about the pertinent instructions show that "the jury actually struggled" with the mens rea issue and what,

exactly, it had to find with regards to mens rea. *Thomas v. Chappell*, 678 F.3d 1086, 1103–04 (9th Cir. 2012) (length of deliberations and jury questions are "objective clues as to the jury's assessment . . . that the case was close"). Thus, it cannot be said that the error was harmless beyond a reasonable doubt. *See id.*

If plain error applies, the result is the same. The error was plain because the court improperly included the bracketed sentence that relieved the government of proving knowledge of unlawfulness, contrary to the model instructions and relevant case law. *Liu*, 731 F.3d at 994–95 (explaining that inclusion of the bracketed sentence in the model instruction for knowingly is in error (and plainly so) where the government has to prove knowledge of unlawfulness). Further, the error affected Schena's substantial rights because it negated the knowledge-of-unlawfulness requirement and "created a genuine possibility that the jury convicted" without finding knowledge of unlawfulness, as discussed above. *Bear*, 439 F.3d at 569–70.

Finally, "allowing [defendant's] conviction to stand, given the likelihood that the jury may not have convicted had they been properly instructed, would seriously affect the fairness, integrity or public

reputation of the judicial proceedings." *Bear*, 439 F.3d at 570–71. While a conviction can stand "when the evidence against the defendant on the issue erroneously explained to the jury is 'overwhelming,'" that only occurs "when the erroneous instruction pertained to a fact that was 'essentially uncontroverted at trial.'" *Id.* at 570 (citation omitted). Here, though, Schena's knowledge of unlawfulness was disputed.

Given that a reasonable jury, properly instructed, could have found that the government failed to prove Schena's knowledge of unlawfulness for Counts 1–6, the convictions should be reversed.

IV. The Evidence was Insufficient for the Securities Fraud Counts (Counts 7–9).

For each of the securities fraud counts, the evidence was insufficient to support the conviction. For these three communications at issue, the government had to prove that each contained an untrue statement, of material fact, made in connection with the purchase or sale of Arrayit securities, for the purpose of defrauding or deceiving someone. 1-ER-256–57, 2-ER-291–93. "[M]ateriality depends on the significance the reasonable investor would place on the withheld or misrepresented information" in making trading decisions. *Basic Inc. v. Levinson*, 485 U.S. 224, 234–36, 240 (1988).

Count 7 concerned a press release on November 19, 2018, announcing an "allergy testing agreement with Sutter Health." 2-ER-292, 10-ER-2684. While the headline and first sentence of the press release suggested a company-wide agreement with Sutter, the second sentence explicitly stated that the allergy testing was being provided "via doctors in the Sutter Health-affiliated Palo Alto Medical Foundation" (PAMF). 10-ER-2684. The rest of the first paragraph included information about the size of Sutter Health as a whole. *Id.*

Even taken in the light most favorable to the government, this press release did not contain a fraudulent misrepresentation. The evidence at trial showed that eight doctors at PAMF signed up to use Arrayit for patients. 6-ER-1491. And while a cursory reading of the press release could leave the impression that Arrayit had entered a larger company-wide agreement, the press release included the crucial detail that the doctors at PAMF would be using the allergy testing. 10-ER-2684, 4-ER-960–61. Thus, "[a] fair reading of the press release," as a whole, simply does not support a finding that it fraudulently misrepresented an agreement with the entire Sutter Health system. *In*

re Sorrento, 97 F.4th at 641 (rejecting a reading of a press release and other materials that did not take the facts in full context).

Count 8 concerned a tweet on August 8, 2019, stating: "Arrayit clinical team commences $240,000,000 test kit manufacturing run to build inventory." 2-ER-292, 10-ER-2683. The two shareholders who testified about this tweet at trial admitted that, while the statement was relevant to them, it did not influence them in relation to buying or selling Arrayit stock. 4-ER-953, 4-ER-961, 5-ER-1343.

Thus, even taking this testimony in the light most favorable to the government, it failed to establish the materiality of the tweet because the investors themselves did not believe that the information in the tweet was significant to their investing decisions. *See Basic*, 485 U.S. at 231–40 (information conveyed must be significant in the larger mix of factors that a reasonable investor would consider in making investment decision). And while materiality is assessed from an objective "reasonable investor" standard, *id.* at 240 & n.18, the government provided no reason to believe that a hypothetical "reasonable investor" would find the tweet more important in making an investment decision than the two investors who testified at trial.

Count 9 concerned "emails to investors about demand for Arrayit's COVID-19 tests and coordination with government agencies sent on or about March 21, 2020." 2-ER-293, 10-ER-2666–82. The emails stated, "Dear Valued Customer, We received more than 50,000 requests for our finger stick blood test for SARS-CoV2, the virus that causes coronavirus disease 2019 (COVID-19). Our team is coordinating with local, state and federal agencies and with our distributors to make this test available to as many patients as possible on an expedited timeline. Please consult our website and press releases for updates." 10-ER-2666. According to the government, this statement was false because the Covid test was not yet ready, did not yet have agency approval, and ultimately failed to get agency approval. 8-ER-2335–38.

However, the statement makes clear that Arrayit was *in the process* of rolling out its Covid test, and it does not misstate that the test was immediately available or that it was already approved. By the time this email was sent, Arrayit had ordered the antigens for its Covid test and had "started building it." 6-ER-1566–70, 9-ER-2623. And a different email a few days later included detailed testing and information pamphlets about the Covid test, which reflects that the test

was more than simply an aspiration on March 21, when the emails at issue were sent. 9-ER-2623–26.

Further, Schena had submitted information about the test to the federal agency BARDA by March 23. 9-ER-2623. And while Arrayit did not submit its application with the FDA until a few weeks later, the emails on March 21 did not misrepresent that Arrayit was further along in the process than it was. Instead, the emails indicated that Arrayit was "coordinating with agencies," which indicates an ongoing process, without any specific steps already accomplished, and which fairly includes the time Arrayit was spending on preparing the materials to send to the agencies. Merriam Webster Online (a gerund "expresses generalized or uncompleted action"); *see also State v. Brady*, 506 P.3d 1180, 1184 (Or. App. 2022) (the use of a gerund "embraces the notion of an ongoing process").

Additionally, the indication that Arrayit was working to make the test available quickly and in large quantities is a "statement of corporate optimism," not a misstatement of current facts. *In re Sorrento*, 97 F.4th at 639, 641–42 (holding that a reasonable person reading the defendants' optimistic statements about the company's

Covid product would not think that it was immediately available and 100% effective). Even taken in the light most favorable to the government, the evidence at trial showed that Schena was working on the Covid test, in the process of trying to gain agency approval, and planning to widely distribute the product, when the statement was sent. 3-ER-677, 6-ER-1566–70, 7-ER-1910, 7-ER-1945, 7-ER-2006, 9-ER-2623–26. Thus, the statement was not fraudulently misleading at the time. *Ronconi v. Larkin*, 253 F.3d 423, 429–30 & nn.l2–13 (9th Cir. 2001) (optimistic corporate predictions do not constitute fraud, and there is no "'fraud by hindsight'" (citations omitted)).

Further, even if "50,000 requests" was an inflated number of inquiries, 4-ER-881, 7-ER-2010–12, that part of the tweet was not the material part. The relevant news was that Arrayit was working on a Covid test, which interested investors because of the undeniable need for Covid tests at that point in time. 4-ER-956, 7-ER-1758. Thus, the material point of the tweet was true: Arrayit was working to distribute a Covid test. *Basic*, 485 U.S. at 240 ("materiality depends on the significance the reasonable investor would place on the withheld or misrepresented information" in making trading decisions).

Finally, although defense counsel failed to move for acquittal on these counts, "a conviction that erroneously rests on insufficient evidence necessarily implicates 'substantial rights' and seriously affects the 'fairness' and 'integrity' of the judicial process." *United States v. Cruz*, 554 F.3d 840, 851 (9th Cir. 2009) (citation omitted). Thus, the insufficiency of the evidence for Counts 7–9 requires reversal.

V. The District Court Erred by Imposing Restitution and Forfeiture for Losses Untethered from Offense Conduct.

The district court imposed a staggering restitution award of nearly $25M against Schena, based on the government's calculation of $21,562,300.81 in shareholder losses and $2,727,240.14 in healthcare insurance losses. 1-ER-12–13. Notably, the district court rejected these very same loss amounts for purposes of calculating the sentencing guidelines, because the government failed to establish that these losses were caused by offense conduct. 1-ER-19–29.

The same problem applies to the restitution order, which must be based "'only [on] the loss[es] caused by the specific conduct that is the basis of the offense of conviction.'" *Batson*, 608 F.3d at 636 (citation omitted) (vacating order of restitution that went beyond the losses from offense conduct). To establish this requisite causal connection between

offense conduct and the losses, the government must "show not only that a particular loss would not have occurred but for the conduct underlying the offense of conviction, but also that the causal nexus between the conduct and the loss is not too attenuated (either factually or temporally)." *United States v. Swor*, 728 F.3d 971, 974 (9th Cir. 2013) (per curiam) (quotation marks and citations omitted). The only circumstance in which a restitution award can encompass losses from non-offense conduct is when "the crime of conviction includes as an element a scheme, conspiracy or pattern of criminal activity." *Batson*, 608 F.3d at 636–37.

Here, however, the securities fraud convictions arose from three specific statements in 2018, 2019, and 2020—not from a sweeping fraud scheme. 2-ER-292–93. Even though the government put on evidence of other purported misstatements by Arrayit, the verdict form focused the jury on finding liability on these three particular misstatements, not on any larger scheme. *See United States v. Southerland*, 209 F. App'x 656, 658 (9th Cir. 2006) ("The purpose of a special verdict form, where used, is to . . . 'encourage[] juries to focus their deliberations on the elements of the offense.'" (quoting *United States v. Poehlman*, 217 F.3d 692, 698

n.7 (9th Cir. 2000)); *United States v. Aguirre*, 4 F. App'x 370, 375 (9th Cir. 2001) ("the special verdict form . . . narrowed the charges," as "is permissible"). Thus, the jury was not asked to find, nor did it find, a larger securities fraud scheme.

And yet, the government made no attempt to link its massive $21.5M shareholder loss calculation to these three statements. 1-ER-20. Instead, the government based its calculation on a five-year period of shareholder investments in Arrayit and assumed that all of the investments turned into losses attributable to Schena. *Id.* Because these losses were not caused by the specific offense conduct, the district court "erred in ordering restitution in an amount beyond the loss sustained . . . as a result of the offense[s] of conviction." *Batson*, 608 F.3d at 637. The restitution order must be vacated on this basis alone.

In any event, there are two additional problems with the shareholder loss calculation. 1-ER-21–22. As the district court pointed out in its sentencing guidelines order, the government failed to substantiate that all investments were ultimately worthless after trading was briefly suspended. *Id.* Even "close to zero is not zero" when it comes to stock value. *United States v. Zolp*, 479 F.3d 715, 720

(9th Cir. 2007) (rejecting the government's assertion that a company's stock was worthless after a suspension of trading because the stock "continued to have some value"). Yet the government made no attempt to estimate the post-suspension value and, thus, failed to justify its use of zero value post-suspension. *See id.* Moreover, the government failed to justify its expert's decision to use the first-in, first-out methodology to calculate loss as opposed to other common methods, such as the modified rescissory method. *See* 1-ER-21–22.

For the healthcare insurance loss amount, the government based its calculation of $2.7M on every dollar of reimbursement that Arrayit received for its allergy and Covid testing services. However, the government failed to establish that the testing services had *no* value. 1-ER-22–25. In fact, the fraud convictions were not based on Arrayit's tests being worthless; they were based on Arrayit's purportedly fraudulent business practices: that Arrayit obtained its CLIA license through fraud; that Arrayit paid its marketers kickbacks; that Arrayit tested for 120 allergens in all cases, which was excessive; and that Arrayit bundled its allergy and Covid test, which was medically unnecessary.

These fraud theories do not suggest that the testing was worthless, or that, but for the alleged fraud, the testing would not have been covered by insurance. Accordingly, the district court abused its discretion in ordering restitution based on all reimbursements, and the order must be vacated. *See United States v. Stone*, 822 F. App'x 624, 626 (9th Cir. 2020) (vacating restitution order where "[t]he government . . . had the burden to prove which portion of the insurance payout was fraudulent" and "did not do so").

Finally, the district court imposed forfeiture for the same $2.7M in reimbursements covered by the restitution order. 1-ER-237–38. Similar to restitution, however, a forfeiture order is limited to "property . . . that constitutes or is derived . . . from gross proceeds traceable to the commission of the offense." 18 U.S.C. § 982(a)(7). For the reasons already discussed, the government did not establish that all the reimbursements for Arrayit's testing were derived from the fraud offenses. Thus, the forfeiture order must be vacated.

CONCLUSION

For the reasons stated, the Court should reverse all counts of conviction, and vacate the restitution and forfeiture orders.

Respectfully submitted,

Dated: May 28, 2024

LEAH SPERO
SPERO LAW OFFICE

By: _____/s/_____
Leah Spero
Attorney for Mark Schena

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form08instructions.pdf

9th Cir. Case Number(s) 23-2989 & 23-3965

I am the attorney or self-represented party.

This brief contains 13,452 **words,** including _____ words manually counted in any visual images, and excluding the items exempted by FRAP 32(f). The brief's type size and typeface comply with FRAP 32(a)(5) and (6).

I certify that this brief *(select only one)*:

- (•) complies with the word limit of Cir. R. 32-1.
- ( ) is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.
- ( ) is an **amicus** brief and complies with the word limit of FRAP 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).
- ( ) is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.
- ( ) complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one)*:
  - [ ] it is a joint brief submitted by separately represented parties.
  - [ ] a party or parties are filing a single brief in response to multiple briefs.
  - [ ] a party or parties are filing a single brief in response to a longer joint brief.
- ( ) complies with the length limit designated by court order dated _____.
- ( ) is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature s/ Leah Spero **Date** 5/28/24
*(use "*s/[typed name]*" to sign electronically-filed documents)*

ADDENDUM

Eliminating Kickbacks in Recovery Act, 18 U.S.C. § 220(a):

(a) Offense. Except as provided in subsection (b), whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully—

(1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or

(2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or

(B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,

shall be fined not more than $ 200,000, imprisoned not more than 10 years, or both, for each occurrence.

MANUAL OF
MODEL CRIMINAL JURY INSTRUCTIONS

FOR THE DISTRICT COURTS OF THE NINTH CIRCUIT

Prepared by the
Ninth Circuit
Jury Instructions Committee

2022 Edition

Last Updated August 2023

4.8 Knowingly

An act is done knowingly if the defendant is aware of the act and does not [act] [fail to act] through ignorance, mistake, or accident. [The government is not required to prove that the defendant knew that [his] [her] acts or omissions were unlawful.] You may consider evidence of the defendant's words, acts, or omissions, along with all the other evidence, in deciding whether the defendant acted knowingly.

Comment

The second sentence of this instruction should not be given when an element of the offense requires the government to prove that the defendant knew that what the defendant did was unlawful. *See United States v. Liu*, 731 F.3d 982, 994-95 (9th Cir. 2013) (criminal copyright infringement); *United States v. Santillan*, 243 F.3d 1125, 1129 (9th Cir. 2001) (violation of Lacey Act). In the context of a money laundering offense, the second sentence of this instruction may be given if altered to clarify that it applies only to the act of engaging in monetary transactions, and not to whether a defendant knew the money involved in the transaction was the proceeds of criminal activity. *Compare United States v. Lonich*, 23 F.4th 881, 897-901 (9th Cir. 2022), *with United States v. Stein*, 37 F.3d 1407, 1409-10 (9th Cir. 1994), *and United States v. Turman*, 122 F.3d 1167, 1169-70 (9th Cir. 1997), *abrogated on other grounds by Henderson v. United States*, 568 U.S. 266 (2013). *See also United States v. Jaimez*, 45 F.4th 1118, 1123 (9th Cir. 2022) (money laundering conspiracy).

Revised Sept. 2022